

510 (k) SUMMARY

K072883

**Arbel Medical Ltd. ICE-SENSE® Device**

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

Manufacturer: Arbel Medical LTD.  
New industrial park 7  
Building 1a  
P.O.Box 620  
Yokneam 206923  
Israel  
Telephone: +972-4-9090000  
Facsimile: +972-4-9090001

DEC 10 2007

Contact Person: Dr. Zvi Ladin PhD.  
Principal Investigator  
Boston MedTech Advisors, Inc.  
990 Washington Street  
Suite #204  
Dedham, MA 02026  
Telephone: (781) 407 0900 x104  
Facsimile: (781) 407 0901  
Email: zladin@bmtadvisors.com

Date Prepared: October 4, 2007

**Name of Device and Name/Address of Sponsor**

Trade/Proprietary Name: Arbel Medical ICE-SENSE® Device

Common Name: Cryosurgical unit and accessories

Classification Name: Cryosurgical unit and accessories (21 C.F.R. § 878.4810)

Manufacturing Facility: Arbel Medical LTD.  
New industrial park 7, Building 1a  
P.O.Box 620  
Yokneam 206923  
Radiancy (Israel) Ltd.

Establishment  
Registration Number: N/A

Owner/operator number: N/A

## **Predicate Devices**

Cryomedical Sciences Cryolite (K970995), Cryomedical Sciences Accuprobe 610 (K964366, K973190) and Galil Medical Cryo-Hit (K980913)

## **Intended Use / Indications for Use**

The ICE-SENSE™ device has the following indications for use:

### Urology

- *The system may be used to ablate prostatic tissue.*
- *The system may be used for the ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia*

### Oncology

- *The system may be used for ablation of cancerous or malignant tissue.*
- *The system may be used for ablation of benign tumors.*
- *The system may be used for palliative intervention.*

### Dermatology

- *The system may be used for the ablation or freezing of skin cancers and other cutaneous disorders.*

### Gynecology

- *The system may be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia.*

### General Surgery

- *The system may be used for the ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocoele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions.*
- *The system may be used for the destruction of warts or lesions.*
- *The system may be used for the palliation of tumors of the oral cavity, rectum, and skin.*

### Thoracic Surgery

- *The system may be used for the ablation of arrhythmic cardiac tissue.*
- *The system may be used for the ablation of cancerous lesions*

### Proctology

- *The system may be used for the ablation of benign or malignant growths of the anus and rectum*
- *The systems may be used for the ablation of hemorrhoids.*

## **Technological Characteristics**

The ICE-SENSE™ Device is used to destroy unwanted tissue by application of extreme cold to the selected site. The device delivers cold temperatures to targeted tissue

by pressurized liquid nitrogen closed system and a disposable sharp or blunt probes. The device consists of a main chassis for the cooling system, a controller with a screen and key pad, a cryohandle that controls and holds the probe and a foot pedal.

### **Substantial Equivalence**

The ICE-SENSE™ has the same intended use and indications for use, principles of operation and technological characteristics as its predicate devices. The slight differences between ICE-SENSE™ and its predicate devices do not raise any new issues of safety and effectiveness.

Arbel's ICE-SENSE™ is substantially equivalent to a combination of the above named predicate devices and the minor differences detailed in the discussion do not raise additional concerns of safety or efficacy.

These are cryosurgical devices that use a coolant to provide a very low temperature to the treated tissue by using a designated probe. The main predicate device is the Cryomedical Sciences' Accuprobe 610. The IceSense is equipped with sharp probes for percutaneous procedures as the Cryo-Hit does. It uses passive thawing and is open loop controlled as does the predicate Cryolite device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 10 2007

Arbel Medical, Ltd.  
% Boston Medtech Advisors, Inc.  
Zvi Ladin, PhD  
990 Washington Street, Suite 204  
Dedham, Massachusetts 02026

Re: K072883  
Trade/Device Name: Arbel ICE-SENSE™  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical unit and accessories  
Regulatory Class: II  
Product Code: GEH  
Dated: October 4, 2007  
Received: October 9, 2007

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K 072883

Device Name: Arbel ICE-SENSE™

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K072883

Page 1 of 2

General Surgery

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Page 2 of 2

510(k) Number  K 072883